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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/871,367      | 05/31/2001  | Katrin Kriwet        | 4-30724A            | 1754             |

1095 7590 07/30/2003

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NOVARTIS, CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

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| EXAMINER |
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KIM, VICKIE Y

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1614

DATE MAILED: 07/30/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/871,367

Applicant(s)

KRIWET ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-41 is/are pending in the application.
- 4a) Of the above claim(s) 14,16,18,20,21,23,25,27,29,31 and 33-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15,17,19,22,24,26,28,30,32 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election acknowledged***

1. Applicants affirmation on the election without traverse of Group II, claims 15,17,19,22,24,26,28,30,32 and 41 and sodium chloride as an elected species is acknowledged. Since applicant's election is made without traverse, the restriction requirement deems proper and made FINAL.
2. Applicant's request on rejoining claim 34 that is directed to a method claim will be reconsider when the allowable subject matter is found. Until then, the claim 34 will be treated as non-elected claim and withdrawn from the consideration.

### ***Status of application***

3. The claims 14-41 are pending. The claims 15,17,19,22,24,26,28,30,32 and 41 are presented for the examination and the claims 14, 16, 18, 20-21, 23, 25, 27, 29, 31, 33-40 are withdrawn from the consideration.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 15, 19, 22, 24, 26, 30 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackman et al(US 6,352,998), or in the alternative, under 35 U.S.C. 103(a) as obvious over Jackman et al(US 6,352,998) in view of Henney et al(abstract only, 1958) and .

The claims are drawn to a Jackman et al teaches a composition for topical administration of 33-epi-chloro-33-desoxy-ascomycin(0.1-2%), which composition comprises a carrier vehicle comprising (i) means to retain water in the outer skin layer(0.1-20%) and (ii) means to hinder water evaporating from the skin(e.g. solid or liquid paraffin, microcrystalline wax).

Jackman et al teaches a composition for topical administration of 33-epi-chloro-33-desoxy-ascomycin(=compound B, see colum 3, lines 40-41) and a carrier comprising akanediol(e.g. propylene glycol), a fatty alcohols(e.g. cetyl alcohol, stearyl alcohol) , a fatty liquid oils(e.g. Miglyol 812), a thickening agent (e.g.paraffin, petrolatum or microcrystalline wax), and so on, see claims. Especially, Jackman contemplates his inventions in examples 23 or 26, wherein the patented composition teach all the critical elements required by the instant claims, for instance, example 26 contains 0.1% of 33-epi-chloro-33-desoxy-ascomycin(=compound B) as an active agent; propylene glycol(5%); paraffin(thick) and fatty alcohols(e.g. cetyl alcohol or stearyl alcohol).

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Although, Jackman indicates that propylene glycol is used as solvent in his patent, it is conventional knowledge that propylene glycol is inherently functioning as a humectant where it prevents superficial water loss from epidermal skin layer(=means to retain water in outer skin layer).

Thus, any skilled artisan readily envisaged that the topical composition of 33-epi-chloro-33-desoxy-ascomycin(=compound B) and a carrier system having propylene glycol to retain water in the outer skin layer and also to solubilize the active agent, paraffin that is to hinder water evaporating from the skin, and optionally a fatty alcohols such as cetyl or stearyl alcohols assisting solubilization of the active agent. Thus, all the critical elements required by the claims are taught by the cited reference.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 17, 28 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackman(US 6,352,998) in view of Eugley (US 4,324,811) and Katzev(US 5,002,760).

Jackman's teaching is mentioned in 102 rejection(supra).

Applicant's claims differ because they require sodium chloride as an inorganic salt to retain water in the outer skin layer, and also isopropyl myristate as a liquid mean used for solubilizing the active agent.

However it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Jackman's teaching to substitute propylene glycol with sodium chloride; and a fatty acid or fatty oil with isopropyl myristate when Jackman is taken in view of Eugley and Katzev because they remedy the deficiency of Jackman's teaching.

Eugley teaches the characteristics of the chemical compounds that are used as a humectant wherein sodium chloride is 2-2.5 times more effective than propylene glycol or glycerol, see column 2, lines 33-45.

Katzev teaches sodium chloride as an effective humectant utilized in skin product, see claim 8. Katzev also teaches that a skin care composition contains humectants selected from sodium salt such as sodium chloride, glycerin, pyrrolidone carboxylic acid or urea, see table at column 2.

It is noted that the major disadvantage of sodium chloride(e.g. flavor problem) mentioned in Eugley's patent is moot because Sodium chloride is used in skin care product but not food product where the flavor is no longer became an issue.

Thus, one would have been motivated to make such substitution, with reasonable expectation of success, because sodium chloride is easy to obtain and considered to be a cost effective.

8. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackman(US 6,352,998) in view of Jones et al(US 4,963,555).

Jackman's teaching is mentioned in 102 rejection(supra).

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Applicant's claims differ because they require isopropyl myristate as a liquid mean that is optionally added to solubilize the active agent.

Jones et al teach that isopropyl myristate is functionally equivalent fatty oil component to the blend of cetyl and stearyl alcohol, wherein it achieves the desired cosmetic properties, see column 3, lines 37-54. It is noted that the solubilizing activity of these fatty components are inherent for the lipid soluble active agent and the minor variations including the selection of optimal species within the same class in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art absent evidence to the contrary, and is obvious.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invent was made to substitute a blend of cetyl and stearyl alcohol(as taught in Jackman Patent , see example 26) with isopropyl myristate because it is simple and well known compound which can be access and available easily. For the convenient or to make cost effective product, one would have been motivated to make such substitution without undue burden. One would have been motivated to combine these references and make the modification, with reasonable expectation of success, because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

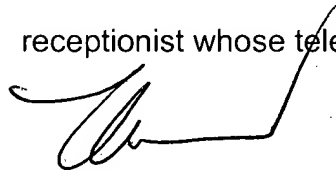
### **Conclusion**

9. No claim is allowed.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675.

The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,  
Patent examiner  
July 28, 2003  
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